

## Meeting Report

# Standardization of Nomenclature in Acupuncture Research (SoNAR)

Peter White<sup>1</sup>, Brenda Golianu<sup>2</sup>, Chris Zaslowski<sup>3</sup> and Choi Seung-Hoon<sup>4</sup>

<sup>1</sup>University of Southampton, UK, <sup>2</sup>Stanford University, USA, <sup>3</sup>University of Technology, Sydney, Australia and <sup>4</sup>Regional Adviser in Traditional Medicine, World Health Organization, Western Pacific Regional Office, Philippines

As more clinical acupuncture trials for pain are published, it becomes increasingly difficult to compare and evaluate the merits and shortcomings of such studies. A major contributory factor to this centers on the description of, and the assumptions made about, the control intervention used. In considering an acupuncture control, it is important to evaluate its physiological activity and thus far, this has not been done. A variety of different and sometimes very novel controls have been tried and used in the research setting and the inevitable consequence of this is confusion, particularly when attempting to interpret the results of trials. Researchers and other interested parties such as patients, primary care practitioners, funding agencies etc., searching for evidence in the literature are likely to be misled or confused by such variability. There is therefore a need to define and standardize many of these terms, to clarify reporting and to convey the correct information in a way that it is not misleading. This paper details the background and need for this and is primarily intended to assist those who intend to publish primary and secondary acupuncture research. However, standardization of reporting will be of benefit to anybody who will need to examine the literature for evidence. This article proposes and recommends a nomenclature when reporting future acupuncture clinical research. This nomenclature arose through discussion at a meeting convened by the World Health Organisation (Western Pacific Regional Office) and will be incorporated into their policy document later this year.

**Keywords:** acupuncture – nomenclature – reporting – RCT – standardization

## Background

Traditional reports of acupuncture usually do not include a control group. The reason for this is that it was considered unethical not to treat a patient. Hence reports generally fell under the category of case studies (individual or series). Intensive research into acupuncture was spurred worldwide with the demonstrations in the 1970s of ‘acupuncture anaesthesia’. Impressive documentation of patients who were able to undergo surgery while relatively awake stimulated scientists to investigate the possible mechanisms of action of acupuncture (1). While it was recognized that clinical examples and case series had validity, the gold standard for the evaluation of efficacy is the randomized controlled trial

(RCT). RCTs and meta-analysis have become the standard of practice for demonstration of clinical effect and the foundation of evidence-based medicine.

Acupuncture research has grown exponentially during the past 10 to 20 years (2). As more clinical trials are published, it becomes increasingly difficult to compare and evaluate the merits and shortcomings of such studies. One reason involves the diverse range of acupuncture traditions that are utilized (3). These include Traditional Chinese Medicine (4), Japanese Meridian therapy (5), Korean Hand Therapy and Four Constitutions (6) to name a few. Another and perhaps more relevant issue centers on the description of the control intervention utilized. In considering acupuncture controls it is important to evaluate the physiological activity of the control intervention, as well as how that control intervention may activate the ‘placebo’ response. Because there is, as yet, no convincing and proven ‘placebo’ for acupuncture, a variety of different and sometimes very novel controls have been tried and used in the research setting (7).

For reprints and all correspondence: Dr Peter White, School of Health Professions and Rehabilitation Sciences, University of Southampton, Highfield, Southampton, SO17 1BJ, UK; Tel: +44 (0)23 8059 8954; Fax: +44 (0)23 8059 5301; E-mail: pjw1@soton.ac.uk

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Early efforts included rubbing the needles on the skin or gluing them to the skin (8,9). The difficulty with these types of controls is that they are not credible. A significant advancement was achieved with the description of the mock transcutaneous electrical nerve stimulation (TENS) control. A TENS unit is attached in the usual way including the application of pads to the skin, however no current is applied (10). This procedure does provide an intervention, yet is still not entirely credible as a control for acupuncture. Placement of needles in the skin has increasingly been required as a control intervention in order to control for the full range of non-specific effects. This practice is usually referred to as 'sham acupuncture'.

'Sham acupuncture' has been defined as 'invasive but inappropriate needling' (11). There is no therapeutic intent in the procedure. Nevertheless, sham acupuncture has important physiologic effects. Lewith and Machin (12) pointed out that sham acupuncture appeared to have an analgesic effect in 40–50% of patients, in comparison with 60% for real acupuncture. The 'sham acupuncture' concept, however, is an important one in that it helps to differentiate non-specific, generalized effects of needling, which include circulatory and immune system changes, diffuse noxious inhibitory control (DNIC), from specific effects (13,14). A wide variety of practices are included under the heading of sham acupuncture.

Previously recognized, different clinical scenarios may require different types of control interventions to mimic a valid treatment (15). Each control intervention has its own advantages and answers a specific research question. For example, a wait list control answers the question 'Is acupuncture better than doing nothing?' while a retractable 'stage dagger' needle such as the Streitberger device (16) assesses 'Is puncturing the skin better than not puncturing the skin?' The inevitable sequela is a certain amount of confusion particularly when attempting to interpret the results of trials. This confusion comes from two areas. Firstly, the researchers themselves will often have limited evidence of the therapeutic activity of the control intervention they are using. This is particularly so if it is a novel control, designed to be a 'placebo' and mimic the sensation of an acupuncture treatment. Very often, no preliminary study will have been conducted to ensure that the intended 'placebo' intervention does not have a physiological or therapeutic effect. Clearly, if a control is thought to be inert, yet is not, this could lead to rejecting the efficacy of the acupuncture intervention, a type II error.

The second group of people who might be confused by such acupuncture trials are the patients, primary care practitioners, specialty providers and funding agencies looking for evidence in the literature. If the researchers themselves have difficulty in interpreting certain trials, then those who do not understand the complex issues surrounding acupuncture research will have a much harder problem when trying to evaluate the evidence presented to them in a trial report or paper. For example, on reading about a trial which uses 'sham acupuncture' as a control, it would be entirely reasonable for a health professional to assume that the word 'sham' denotes

that the control was inert, i.e. a placebo, and therefore base their conclusions around this premise. Yet the term 'sham acupuncture' has been used to describe a multitude of different procedures, ranging from insertion of needles at non-acupuncture points (17) (including non-auricular acupuncture points (18)), insertion of needles superficially at acupoints and non-acupoints, using special devices that mimic the insertion of a needle but do not pierce the skin, needling at acupuncture points that are believed to be non-therapeutic for the condition under examination, through to pricking the skin with a cocktail stick (19) or guide tube (20).

It is not known how physiologically 'active' some of these controls might be and there is fairly strong evidence that they might indeed have a specific physiological effect through mechanisms such as DNIC and pain gate (21). Indeed, those who practice some styles of Japanese acupuncture, such as *Toyo Hari*, would argue that needles do not need to penetrate the skin more than 1 or 2 mm, if at all, to be effective. Hence, it is extremely difficult to say with certainty that any such interventions are therapeutically inert, despite the implication given by the term 'sham'.

Equally, what actually constitutes acupuncture is similarly perplexing. For example the application of LASER to acupoints have been included under the umbrella heading of acupuncture (22,23) even though it does not utilize needles. As acupuncture has been increasingly used in many different countries, the modality has evolved, resulting in a diversity of different practices. Thus, even within the 'generally accepted' field of acupuncture, there are many different styles, techniques and practices, each with its own philosophy and methodology. This again has made it difficult to specifically define the term acupuncture.

It would seem clear therefore, that in terms of reporting and assisting the acupuncture research naive reader, it is necessary to evolve a more clear terminology, to define and standardize many of these terms, to clarify reporting and to convey the correct information in a way that it is not misleading. Comment on the specific effects of various control treatments is beyond the scope of this study. The aim however is to describe a nomenclature that is sufficiently broad to encompass the range of interventions used, particularly control interventions, yet does not use wording which causes confusion. Neither does it seek to comment on the efficacy or practice of the various forms of acupuncture in current use. The study is therefore intended to assist those who intend to report primary and secondary research in the media. Ultimately, this will be of benefit to anybody who will need to examine the literature for evidence.

## Standardization of Terms

The following terms are therefore proposed and recommended when reporting future acupuncture clinical research. This nomenclature was initially proposed by the authors (who were charged with this task) and presented at an open meeting convened by the World Health Organisation (WHO) Western

Pacific Regional Office (WPRO) for the revision of the 'Guidelines for Clinical Research on Acupuncture' in Seoul, Republic of Korea, during August 24–26, 2005. The nomenclature was then discussed at the meeting, which included 25 delegates from around the world. The definitions were then modified where appropriate in the light of discussion. This nomenclature will be published in the new Guidelines, due in 2006.

- Acupuncture—the use of an acupuncture needle to stimulate an acupuncture point or other part of the body for therapeutic purposes. This usually involves puncturing the skin. There is an established underlying body of knowledge that dictates the placement of the needle. The term 'Acupuncture' therefore encompasses the practices of Chinese, Korean, Japanese and 'Western' acupuncture. Use of the acupuncture needle however, is key to this definition.
- Verum (real) Acupuncture—A needling intervention, intended to have a specific therapeutic effect.
- Placebo—An intervention that is known to have no 'specific' therapeutic effect.
- Invasive needle control—An intervention that involves puncture of the skin with an acupuncture needle for the purposes of providing a comparative control. This might be at either acupuncture or non-acupuncture sites and to varying depth. This might also involve varying levels of needle manipulation or stimulation. The therapeutic value of these types of interventions is unknown; however, they are not thought to be placebo interventions given that they probably have some specific physiological effects. This type of control would be useful to test point or even depth specificity but would not yield useful data on pure efficacy.
- Dummy needling control—A non-invasive intervention, designed to mimic verum acupuncture in terms of sensation and/or appearance. This might be at either acupuncture or non-acupuncture sites. This would include interventions such as the Streitberger (16) or Park (24) needle, pricking with a cocktail stick (while blindfolding the patient) etc. While the 'specific' therapeutic effects of such controls are unknown, there is some evidence to suggest that the physiological effect may be different to that of verum acupuncture (25). These forms of control might therefore be useful in an efficacy study, but more validation is needed before any firm conclusions can be drawn.
- Non-acupuncture-like placebo control—An inert intervention which does not attempt to mimic the sensation or appearance of acupuncture. This term includes devices such as mock (deactivated) electrical stimulation of acupuncture points, mock (deactivated) laser to acupuncture points etc. Because these devices are inert, they can correctly be called a placebo. This type of control would be useful in an efficacy study. They might have an effect on some of the psychological aspects of treatment such as

expectation and belief. However, as they do not attempt to mimic acupuncture, they do not therefore control for all of the non-specific effects of needling and thus can only give a partial answer to the question of efficacy. This is particularly so if, as has been suggested, the use of needles might have an enhanced non-specific effect (26).

## Conclusion and Recommendations

The type of control used is dependent on the research question being asked and it is expected that acupuncture research will continue to adopt a range of different controls. The use of the above terms however, is recommended to resolve confusion when reporting acupuncture research. They are considerably less confusing than currently used terms such as *sham acupuncture*, are explicit in term description and will aid the researcher and reader when evaluating the efficacy and/or clinical significance of the published study. They are however not sufficient on their own and they should be accompanied with a detailed explanation of the exact procedure in the text of a study. This should also be accompanied with a short description as to the state of knowledge on how 'physiologically active or inert' the control in question is thought to be. The use of guidelines such as STRICTA (27) is also to be recommended to aid this process.

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